

Impact of follow-up on the success rate of the cryosurgical maze procedure in patients with rheumatic heart disease and enlarged atria

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Objectives: The most important predictors for failure of the maze procedure are long standing atrial fibrillation (AF), rheumatic heart disease (RHD), and enlarged atria. It is well documented, however, that some patients have recurrence of atrial arrhythmia only late in follow-up. The aims of this study are to assess the effectiveness of the maze procedure and late cardioversion (pharmacologic or electrical) in patients with an increased risk for procedure failure.

Patients and Methods: Fifty-five patients with AF, enlarged left atrium (>5 cm), and/or RHD were enrolled in the study. Cryosurgery was performed on all patients and was combined with bipolar radiofrequency in the last four patients. The lesion pattern resembles the maze procedure. A follow-up was completed on all patients (24.5 ± 9.6 months with a range of 3-39 months).

Results: The operative mortality was 3.7% (2 patients), both deaths unrelated to the maze procedure. Ninety-eight percent of patients were free of AF upon discharge, with an 11% incidence of early pacemaker implantation. In the first three months postoperatively, 53% of the patients experienced intermittent atrial arrhythmia. Four patients were recorded with permanent AF in late follow-up. The only predictor for late AF (>3 months of follow-up) was perioperative AF. Atrial size, RHD, and AF duration did not predict late failure.

Conclusions: The maze procedure can be applied with high success rate in patients with RHD, enlarged atria, and long-standing AF. In our experience many of the late recurrences were recorded late in the follow-up and were treated successfully with antiarrhythmic drugs and/or cardioversion. Therefore a close follow-up is required to enhance the success rate of the procedure.

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The maze procedure is recognized as the most effective surgical procedure to treat all types of atrial fibrillation (AF), with a reported long-term success rate in excess of 90%.^{1,2} Recent reports clearly show that the success rate may be significantly lower in a subgroup of patients with longstanding AF, enlarged left atrium, and rheumatic heart disease (RHD).³⁻⁵ It is reported that some patients experience recurrence of atrial arrhythmias only late in the follow-up phase.³ The common practice in such instances is to not take any action in an effort to restore sinus rhythm because the procedure has likely failed. However, in many cases this assumption is not valid. On the basis of other reports, it is important to make every effort to restore sinus rhythm and improve the long-term outcome of these patients.⁶⁻⁸ The aims of this study were to assess (1) the effectiveness of the maze procedure in a group of patients, all of whom had at least 1 traditional risk factor for procedural failure, and (2) the efficacy of a late intervention to reestablish sinus rhythm using antiarrhythmic drugs and/or cardioversion.

Abbreviations and Acronyms

AF	= atrial fibrillation
OR	= odds ratio
RHD	= rheumatic heart disease

Methods

Fifty-five patients with AF, RHD, and/or left atrial size larger than 5 cm were enrolled in the study (Tables 1 and 2). The surgical ablation protocol was based on the Maze III lesion pattern. The only modification that was applied to the Maze III procedure was around the pulmonary veins. Instead of the box lesion around the pulmonary veins, we isolated the right and left pulmonary veins and then applied the connecting lesion between the right and left inferior pulmonary veins (Maze IV).⁹ In this study we used the cryotechnology by Cooper Surgical (Shelton, Conn) as the only ablative technology in all patients except for the last 4 in whom we combined it with bipolar radiofrequency ablation by AtriCure, Inc (Cincinnati, Ohio).

The maze procedure was performed only if patients had a history of AF (continuous or intermittent) for more than 3 months. The procedure was performed as an isolated procedure in only 2 patients; therefore, the majority of the patients in this series had another indication for open surgery in addition to AF. A mean follow-up of 24.5 ± 9.6 months (3-39 months) was completed for the entire group of patients. The end points for the study were mortality and major morbidity events, atrial arrhythmia, the use of antiarrhythmic drugs late in the follow-up phase, and repeated surgical procedures. Events recorded during the first 3 months postoperatively were defined as "early events," and those recorded later were defined as "late events."

Forty-eight patients had at least 1 Holter monitoring during their follow-up. Otherwise, rhythm was recorded every 3 months using repeated electrocardiogram strips.

Antiarrhythmic Treatment and Management of Recurrent Arrhythmia

In general, there is no clear policy to guide the use of antiarrhythmic drugs in patients after the maze procedure. Our policy is based

TABLE 1. Patients' characteristics

Age (y) (median, range)	59.4 \pm 11.6 (59, 39-77)
Female (%)	58.2
Permanent AF (%)	67.3
Duration (y) (range)	5.7 \pm 5.0 (0.25-25)
Persistent or paroxysmal AF (%)	32.7
Duration (y) (range)	3.8 \pm 3.5 (0.25-10)
Rheumatic heart disease (%)	67.3
Mean left atrial diameter (cm) (median, range)	6.3 \pm 0.8 (6.4, 5.2-9.1)
Concomitant surgical procedure (%)	96
Repeated surgery (%)	16.4
Average follow-up (mo) (median, range)	24.5 \pm 9.6 (27, 3-39)

AF, atrial fibrillation.

TABLE 2. Surgical procedures

Surgical procedure	No. of patients	Percent (%)
Maze only	2	3.6
Maze + MVR	17	31
Maze + MVR + tricuspid valve surgery	16*	29
Maze + MV repair	4	7.3
Maze + CABG	2	3.6
Maze + CABG + valve surgery	5	9.1
Maze + AVR	4	7.3
Maze + AVR + MVR	5**	9.1

MVR, Mitral valve replacement; MV, mitral valve; CABG, coronary artery bypass graft; AVR, aortic valve replacement. *Tricuspid valve repair = 15, tricuspid valve replacement = 1. **Combined with tricuspid valve replacement.

on our experience with patients and is as follows (Figure 1). Patients with a history of permanent AF, an enlarged left atrium, and history of RHD are discharged from the hospital with antiarrhythmic drug treatment for 3 months. Amiodarone and sotalol are the drugs of choice. After this 3-month period the drug should be discontinued, and follow-up of the heart rhythm should be conducted using a Holter monitor. If a patient fails to maintain sinus rhythm, we resume antiarrhythmic treatment and attempt electrical cardioversion if required.

The type of antiarrhythmic drug was changed only if a patient experienced a recurrence of arrhythmia while treated accurately with a given drug. Electrical cardioversion was offered to patients who failed to maintain sinus rhythm even if they were late in the follow-up. The first attempt was performed without any changes in the oral antiarrhythmic drug treatment or after a loading dose of amiodarone (if a given patient was not taking any antiarrhythmic medication).

In case of recurrent atrial arrhythmia, we tried 2 different antiarrhythmic drug regimens and 3 different attempts of electrical cardioversion before stating a procedural failure. We attempted rate control on all our patients who did not maintain sinus rhythm with the use of beta- and calcium-blockers.

Statistical Analysis

Data were collected in Microsoft Excel (Microsoft Co, Redmond, Wash) and analyzed in Statistical Analysis Software (Version 8.02, Cary, NC). Continuous data are expressed as mean \pm standard deviation. Categorical data are expressed as frequency and percentage. Unconditional logistic regression was used to examine predictors of recurrent AF and are reported as odds ratios (OR) and 95% confidence intervals. The maximum number of predictor variables in any of the multivariate analysis was restricted to 6 (as suggested by the cumulative rule of no more than 10 subjects per modeled predictor). Kaplan-Meier estimates were used to depict freedom from permanent atrial arrhythmia. Because of the population-based nature of this study, no power analysis was attempted. Given the low event rate and long-term follow-up required, our center would most likely never meet the calculated sample size requirements. A decision was made to present our findings as soon as a relatively large number of patients were seen and followed for a minimally acceptable length of time.

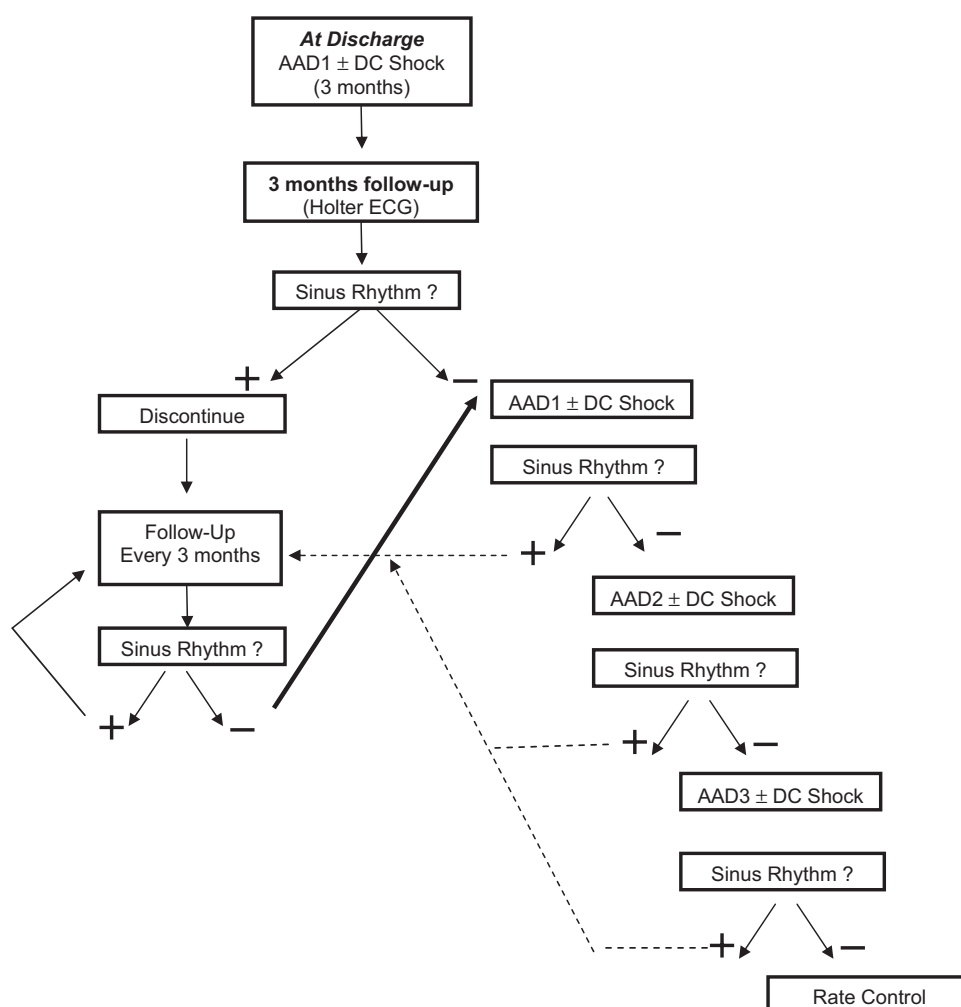


Figure 1. Arrhythmia follow-up and treatment in patients after the maze procedure. AAD, Antiarrhythmic drug; DC shock, electrical cardioversion; ECG, electrocardiogram.

Results

Institutional board review approval for the study was obtained.

Mortality and Major Morbidity Events

The operative mortality was 3.7% (2 patients); therefore, 53 patients entered the follow-up phase. No late mortality was recorded during the follow-up.

Repeated Surgical Intervention

Severe tricuspid insufficiency developed in 1 patient who underwent the maze procedure combined with mitral valve replacement, necessitating tricuspid valve repair 15 months after the original procedure. Significant left anterior descending artery stenosis (the left anterior descending artery was not bypassed during the surgery) developed in 1 patient who had a combined procedure of redo coronary artery bypass grafting, mitral valve replacement, tricuspid valve

repair, and the maze procedure, necessitating a stent implantation to the left anterior descending artery.

Recurrence of Atrial Arrhythmia

Recurring atrial arrhythmia after the maze procedure is not always AF. There are cases of atrial flutter alone, combined AF and atrial flutter, and atrial tachycardia.¹⁰ In this study we refer to events of recurrence as atrial arrhythmia. Atrial arrhythmia recorded during the first 3 months postoperatively is considered early, and events recorded later are documented as late atrial arrhythmia.

Ninety-eight percent of the patients were free of AF on hospital discharge. Six patients (11%) had a pacemaker implantation before hospital discharge for sinus node dysfunction and bradycardia requiring atrial pacing. Fifty-three percent (28) of the patients experienced atrial arrhythmia

TABLE 3. Univariate predictors of any recurrent atrial arrhythmia (>3 months)

Parameter	OR	95% CI	Statistical significance
Age (y)	1.02	0.97-1.07	NS
Female	0.81	0.34-1.91	NS
Atrial size (cm)	1.56	0.69-3.52	NS
RHD	5.85	0.66-55.92	NS
Preoperative stroke	0.81	0.08-8.16	NS
CHF	0.22	0.04-1.17	NS
PAP	1.04	0.47-2.34	NS
Redo surgery	2.50	0.36-17.60	NS
Perioperative AF (<3 mo)	12.21	1.38-107.87	*
Chronic preoperative AF	2.30	0.54-9.76	NS
Paroxysmal preoperative AF	0.44	0.10-1.84	NS
Chronic preoperative AF duration	1.08	0.91-1.28	NS
Paroxysmal preoperative AF duration	1.18	0.95-1.48	NS

OR, Odds ratio; CI, confidence interval; RHD, rheumatic heart disease; CHF, congestive heart failure; PAP, pulmonary arterial pressure; AF, atrial fibrillation; NS, not significant.

during the first 3 months after surgery. All of them were treated successfully either with antiarrhythmic drugs alone (21 patients) or a combination of antiarrhythmic drugs and electrical cardioversion (7 patients).

Late Atrial Arrhythmia

The median time to experience late AF was 4.5 months for females and 10.5 months for males ($P < .025$). Seventeen patients experienced 28 events of intermittent AF (persistent or paroxysmal AF), and all except 1 converted back to sinus rhythm with medications and/or cardioversion. Antiarrhythmic drug therapy as the only treatment was successful in 5 events, and a combination of drug therapy and cardioversion was successful in 22 events. Of the 22 events, 9 were treated with a single drug and 1 electrical cardioversion session, 7 were treated with a single drug and 2 electrical cardiover-

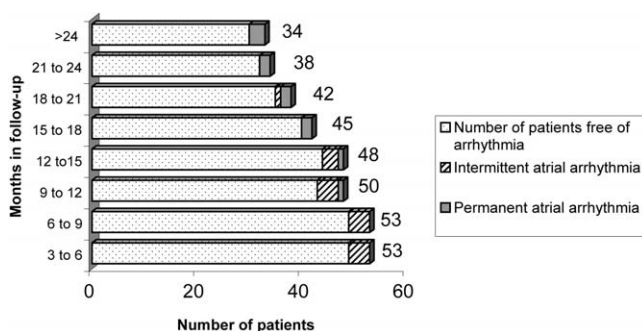


Figure 2. Atrial arrhythmia during follow-up. Total number of patients in follow-up (numbers on right).

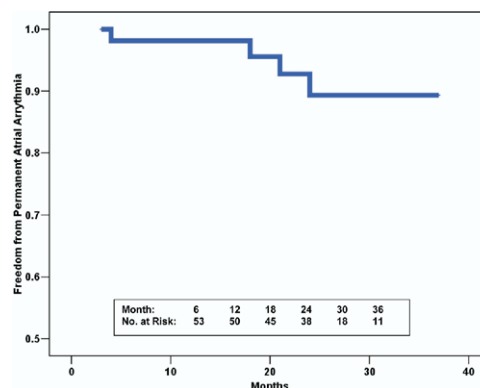


Figure 3. Kaplan-Meier estimates to depict freedom from permanent atrial arrhythmia.

sion sessions, and 6 were treated by replacement of the antiarrhythmic drug and 3 electrical cardioversion attempts. There was 1 failure in conversion back to sinus rhythm. This patient was treated with sotalol and 1 electrical cardioversion, after which severe bradycardia and cardiogenic shock developed. After the patient recovered, no attempts of rhythm control were made, and she is currently in rate-controlled AF.

The only predictor for any late intermittent or permanent atrial arrhythmia (>3 months of follow-up) is perioperative AF (Table 3). We also used a set of clinical variables and tested whether their interaction could predict late recurrence. The variables were age, gender, RHD, atrial size, repeated procedure, type of AF, and duration of AF. In this study none of the interactions were found to be a significant predictor for recurrence of atrial arrhythmia.

Eighty-five percent of intermittent atrial arrhythmia events were recorded during the first year postoperatively with no such event recorded in patients with a follow-up more than 24 months (Figure 2). In univariate and multivariate models no significant predictor for recurrent intermittent atrial arrhythmia was identified.

Four patients have had a recurrence of permanent atrial arrhythmia, all but 1 with RHD. All patients but 1 were treated with our antiarrhythmic protocol, which includes a combination of drug therapy and electrical cardioversion. One patient was treated with oral amiodarone only because of his refusal to be electrically cardioverted.

In a univariate model preoperative stroke was found to be a predictor of late permanent atrial arrhythmia. In a multivariate model using 6 clinically relevant parameters (RHD, redo surgery, left atrial size, perioperative AF, duration of preoperative permanent AF, and intermittent AF), no significant predictors were identified. When left atrial size was examined using size categories (5-6 cm; 6-6.9 cm; >7 cm), no significant atrial size was found to be a predictor of late recurrence of permanent atrial arrhythmia.

Figure 2 shows the recurrence of intermittent and permanent atrial arrhythmia recurrence. Figure 3 shows the Kaplan-Meier estimates for freedom from permanent atrial arrhythmia after the maze procedure.

Long-Term Use of Antiarrhythmic Drugs

Analysis to find predictors for late use of antiarrhythmic drugs was performed using the same set of variables. In univariate and multivariate models, left atrial size and perioperative AF were found to be predictors of long-term antiarrhythmic drug treatment (21% for patients with a follow-up > 24 months). When left atrial size was analyzed using size categories (5-6 cm; 6-6.9 cm; ≥ 7 cm), only left atrial size greater than 7 cm was found as a significant predictor for late use of antiarrhythmic drugs.

All patients who were treated with antiarrhythmic drugs late in the follow-up are those who experienced late arrhythmia recurrence. As a clinician there is a reluctance to stop the medication in this special subgroup of patients after successful cardioversion back to sinus rhythm.

Discussion

The maze procedure has become the most successful surgical treatment for medically refractory AF.^{1,11,12} A subgroup of patients carry a higher risk for failure even when the maze procedure is performed adequately. These are patients with RHD, enlarged left atrium, and longer duration of AF.^{3,5,9} It is, however, important to identify the risk factors for failure of the maze procedure and subsequently adjust the treatment, even late in the follow-up phase. In this study we present the results of a group of patients in whom AF is considered very difficult to treat. We are aware that some of the findings in this study may not be completely in line with the other reports regarding surgery for AF simply because of the bias that may be caused by preselecting only high-risk patients for this report. In our series we did not find any clinically significant predictors for late failure for the following reasons: (1) The study group, in general, was composed of patients who are at an increased risk for failure. For example, the mean left atrial size was 6.3 cm and 67% of the patients experienced RHD (Table 1); thus, all patients who failed either intermittently or permanently carried at least 1 recognized risk factor for procedural failure. (2) The series was small, and the number of events may not have been sufficient to reach significance.

We caution readers to note that although ORs exceeding 2.0 are provocative and highly suggestive of a direction of magnitude, ORs are only statistically significant when the confidence intervals do not contain 1, or unity. Small sample sizes, such as in this study, may lead to larger ORs and increased variances. As a result of these increased variances, statistical significance is usually not met.

However, despite this, the significance of this report lies in the fact that we were able to restore sinus rhythm in most of the patients who failed late in the follow-up phase. As an example, 4 patients had experienced persistent AF during the second year of the follow-up. Sinus rhythm was restored in all of them with antiarrhythmic drug treatment and/or electrical cardioversion.

An interesting finding in our study is gender differences in time to late arrhythmia event. On the basis of our patient population, we do not have any explanation for this unique finding, and we speculate that it may be coincidental.

A better understanding of the mechanism of late failures of the maze procedure is challenging. The most common explanation for late failure is associated with left atrial size. The basic theory claims that if the left atrium is larger than 6 cm, then the ablation lines of the maze procedure do not interrupt the reentry circuits because they are too far apart. Therefore the procedure fails in a higher percentage of cases. If this theory is correct, then why do many of the patients maintain their sinus rhythm until late in the follow-up and experience a recurrence of atrial arrhythmia only late in the follow-up? One explanation may be that the left atrium continues to dilate after surgery, causing a recurrence of AF. However, our experience, as well as the experiences of others, illustrates the opposite. The left and right atrial sizes are significantly reduced after the procedure,¹³ especially in patients who have undergone mitral valve surgery that restored the function of the valve.

Another possible explanation for late recurrence of atrial arrhythmias could be based on a better understanding of the degree of atrial remodeling and its degree of reversibility at the time of the maze procedure. AF usually occurs in the context of an atrial substrate produced by alterations in atrial tissue properties referred to as remodeling. Atrial remodeling has different causes, for example, cardiac disease (congestive heart failure), cardiac arrhythmia, and other biologic processes. Two different types of remodeling have been reported in animal models of AF: ionic remodeling, which affects cellular electrical properties (shortening of atrial refractoriness), and structural remodeling, which brings significant changes to atrial tissue architecture.¹⁴ Long-lasting episodes of AF in an animal model are mainly promoted by conduction disturbances. Repeated episodes of AF result in chronic atrial stretch, which leads to atrial cellular hypertrophy and fibrosis.¹⁵

As in this study, the maze procedure is performed in many patients late in the course of the AF and/or the valvular heart disease. In this case it is likely that the size of the atrium only mirrors the degree of atrial tissue remodeling and disease, and that in many cases the process is not fully reversible.¹⁶ Patients do fail the procedure late in the follow-up phase because the surgical procedure does not lead to total reversal of the remodeling process. Some

patients are left with a significant amount of atrial tissue, which is more susceptible to arrhythmia, even with a minimal challenge.^{17,18} In light of this, the early and late success rates of the maze procedure may be significantly improved by earlier intervention.^{9,19}

This series of patients is very challenging. During the follow-up we were especially active in treating patients with arrhythmia recurrences, even late in the follow-up phase. Thus, we have resumed the antiarrhythmic treatment in some patients. A predictor for the use of antiarrhythmic drugs late in the follow-up is left atrial size, especially larger than 7 cm. However, it was not a predictor for late failure, perhaps because of the higher rate of use of antiarrhythmic drugs late in the follow-up (55%; 5/9 patients with left atrium >7 cm). It is clear now that a subgroup of patients with an enlarged left atrium and severely diseased atrial substrate need to receive antiarrhythmic treatment for an extended period of time (which cannot be defined as of yet). As mentioned, a better understanding of the remodeling process may extend our ability to adjust the postoperative care.

Therefore, it is logical that a rigid follow-up, even later in the postoperative course, is mandatory to enhance the success rate of the procedure. Late arrhythmias during the follow-up phase should be dealt with in a uniform way to enhance success and improve the outcome of patients.^{7,8} An open discussion is necessary to develop a protocol for follow-up for patients after the maze procedure.

In summary, this study shows that the surgical treatment of AF can be effective in patients with risk factors for failure. The success rate can be improved by active treatment of the arrhythmia when it reoccurs. Follow-up clinics for patients after the maze procedure should be established to facilitate a more uniform approach to the care of these patients.

Study Limitations

In this study we present the results of the maze procedure in a unique subgroup of patients with high risk of failure. The study size is fairly small, and the follow-up is not as long as in other studies.⁹ Because of the nature of the study, some of the predictors for the different end points of the study may be different from those in the current literature.

Our follow-up included an early Holter monitoring (>3 months after surgery) and repeated electrocardiogram. This method of rhythm monitoring is common, although very limited. We are pleased with the high rate of initial Holter monitoring; however, on the basis of the recent publication we believe that future reports should include a longer monitoring period using event recorders or long-term Holter monitoring devices.²⁰

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Discussion

Dr. Millar. I congratulate the authors in presenting a group of patients with the predicted worst outcome of atrial fibrillation surgery, this being patients with rheumatic fever and/or enlarged left atria. I have a few questions.

Did you encounter in any of these patients, this is obviously a selected group, those with heavily fibrotic or calcified left atria, and did you include or exclude those patients from this group?

Dr. Ad. In general, we are very aggressive in treating atrial fibrillation surgically and we do operate on every patient with a significant atrial fibrillation history for longer than 3 months. The only real contraindication for performing the maze procedure is calcified left atrium. We may always argue, however, about the success rate of the procedure when performed in patients with enlarged and fibrotic left atrium. In this series patients with fibrotic atrium were included; I don't have the numbers, since we never send atrial tissue for pathology.

Dr. Millar. The second question, you reported 98% of your patients were free of atrial fibrillation on discharge from the hospital, yet in the first three months 53% had recurrent atrial arrhythmias during that first three-month period. Are all patients on amiodarone postop? For how long? How aggressive are you with cardioversion during the hospital stay itself?

Dr. Ad. I believe that your question is very important, and I am glad you have asked it. In recent months we changed our practice and do discharge more patients with atrial arrhythmia provided they are rate controlled, simply because we found that the patients can go home earlier and that the success rate of the cardioversion is much higher if performed three to six weeks postoperatively. All the patients are being discharged on amiodarone or other type of anti-arrhythmic drug and are kept on it for three to six months.

Dr. Millar. In this 53% that had recurrent atrial fibrillation during the first three months, how do you alter your antiarrhythmic treatment if they're all on amiodarone to begin with? Do you give them the rebolus or increase the dosage or just go to cardioversion?

Dr. Ad. Basically, we won't change the amiodarone treatment. We keep the patients on the drug; however, before cardioversion we make sure that they are well loaded with it. In case of a failed cardioversion the anti-arrhythmic would be changed following a required period of window. The second choice of drug is sotalol.

Dr. Millar. Thank you. Your paper really does encourage the need for long-term followup in patients with atrial arrhythmia surgery. Too often our cardiology colleagues see them back in atrial fibrillation early and say, oh, it failed, that's it, put them back on Coumadin and forget about it. Unless we as surgeons educate our cardiology colleagues and/or follow these patients ourselves, we will lose the opportunity to convert many of these back to sinus

mechanism. Often we are much closer than you think and even those that recur late, up to a year, often just restarting an antiarrhythmic agent, they will convert spontaneously. This is what you've shown I agree wholeheartedly. There is a small group of patients that have as you say atrial arrhythmias that are sinus tachycardias or are atrial flutter and these often can be managed very well by cooperation with our electrophysiology colleagues with a very minor ablative procedure. Often we miss getting high enough in the superior or inferior vena cava, a very common place for a flutter mechanism that can be ablated easily.

I congratulate you on your efforts and your emphasis on late followup and persistence in trying to get these patients back into sinus rhythm. I thank the association for the opportunity to discuss the paper.

Dr. Ad. Thank you.

Dr. Misbach. When I hear you say that the early postoperative atrial fibrillation is a predictor of late failure, that's a little bit different than what I've been hearing at meetings in recent years. Do you think that this early recurrence actually changes what happens later, that atrial fibrillation begets atrial fibrillation and that your aggressiveness or lack of aggressiveness that we might have in the first month after surgery has any effect on the long-term outcome, or is this simply a reflection of what remodeling has already occurred before the intervention?

Dr. Ad. I think that you brought up a very good point. This group of patients is unique, and I do believe that the more aggressive we are in treating post-operative arrhythmia the better we are. This may also be applied to other patients, since I believe that atrial fibrillation serves as a final common pathway to quite a few different processes and it is to some extent a cardiomyopathy of the atrial tissue. The problem is that right now we don't know enough to support any assumption. Based on our experience we can say that you can keep more patients out of atrial fibrillation if you address the arrhythmia repeatedly throughout the post-operative period.

Dr. Misbach. That was really—my next question is, if you've had them on amiodarone routinely postoperatively and we've had say 1 or 2 cardioversions and then you add another drug such as sotalol and you discharge them in atrial fibrillation, how long would you wait before cardioverting them again? One week? One month?

Dr. Ad. About 4 to 6 weeks. Usually I use amiodarone to save hospital days, since with sotalol you have to wait 72 hours to make sure that no long QT interval was developed. As mentioned, if they fail cardioversion on drug A we do treat them with a second drug and cardiovert them when loaded.